



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/539,377

01/18/2006

Stuart Bevan

SCRIP 1600-1

6746

28213 7590 02/27/2008

DLA PIPER US LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

02/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/539,377 | Applicant(s) BEVAN ET AL. | |
| | Examiner JON M. LOCKARD | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment</u> |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-4, in the reply filed on 04 January 2008 is acknowledged. Applicant's election of SEQ ID NO:2 in the reply filed on 04 January 2008 is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 3 and 5-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04 January 2008.
3. The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, and/or Claims

4. The response filed on 04 January 2008 has been entered in full. Claims 3 and 5-23 are withdrawn from further consideration as discussed *supra*. Therefore, claims 1-23 are pending, and claims 1-2 and 4 are the subject of this Office action. It is noted that the elected invention is the polypeptide of SEQ ID NO:2, and the claims have been examined to the extent that they read upon the elected invention.

Drawings

5. The Drawings are objected to for the following informalities:
6. Figures 1B-1, 1B-2, 5, and 7 are objected to because 37 CFR 1.84 states that "[P]artial

Art Unit: 1647

views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter”.

7. The drawings are objected to because Figure 1 has two parts (1B-1 and 1B-2), Figure 7A has two parts, and Figure 7B has two parts; however the brief description of the drawings does not describe all the parts or the Drawings (Figure 7A-D) do not label all of the parts. Applicant is reminded that MPEP 601.01(g) states "[I]f the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected.

8. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should *not* be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Art Unit: 1647

9. The disclosure is objected to because of the following informalities:

10. The Specification at pg 2 discloses that “translation of the mouse nucleotide sequence predicts a protein of 1125 amino acid residues (SEQ ID NO:1), very similar to human ANKTM1 (1119 amino acids) (SEQ ID NO:2)”. However, the sequence listing discloses that the protein of SEQ ID NO:1 has 320 amino acid residues and SEQ ID NO:2 has 319 amino acid residues. Appropriate correction is suggested.

Claim Objections

11. Claim 2 is objected to because of the following informalities: Claim 2 encompasses non-elected inventions, e.g., SEQ ID NO:1. Appropriate correction is suggested.

Claim Rejections - 35 USC § 112, 1st Paragraph (Written Description)

12. Claims 1-2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. Claims 1-2 and 4 are drawn quite broadly to an isolated nucleic acid encoding an ANKTM1-related polypeptide, characterized as encoding a temperature/pain sensitive non-selective cation channel protein that is activated by temperature below 20 °C; being expressed in Calcitonin gene-related peptide- and substance P-positive neurons; and comprising more than five ankyrin domains and a six transmembrane domain. The claims also wherein the nucleic acid encodes a ANKTM1-related polypeptide comprising an amino acid sequence selected from SEQ

Art Unit: 1647

ID NO:1, SEQ ID NO:2, and conservative variations thereof; and wherein the ANKTM1-related polypeptide comprises the amino acid sequence of SEQ ID NO:2, or a conservative variation thereof. Thus, the claims are drawn to a genus of polypeptides that are defined only by a partial structure.

14. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure and function. However, there is not an identification of any particular portion of the structure that must be conserved in order to provide for the recited function.

15. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one protein species (SEQ ID NO:2) is not adequate written description of an entire genus of functionally equivalent polypeptides, which incorporate all variants, derivatives, and homologs encompassed by the claims.

16. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed” (See page 1117). The specification does not “clearly allow persons of

Art Unit: 1647

ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

17. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

18. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

19. Therefore, only an isolated protein comprising/consisting the amino acid sequence SEQ ID NO:2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaquemar et al. (J. Biol. Chem. 274(11):7325-7333, published 12 March 1999).

22. Jaquemar et al. disclose an isolated nucleic acid sequence that encodes a polypeptide (See Fig. 1) that comprises an amino acid sequence that shares 100% sequence identity to SEQ ID NO:2 of the instant application (See attached sequence alignment). While Jaquemar et al. is silent with regard to the encoded polypeptide being a temperature/pain sensitive non-selective cation channel protein that is activated by temperature below 20 °C, and being expressed in Calcitonin gene-related peptide- and substance P-positive neurons, it is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971)). Thus, stating a new property of the polynucleotide or the encoded polypeptide of Jaquemar et al. does not render the polynucleotide or the encoded polypeptide of the instant application free of the art. Thus, the Jaquemar et al. reference meets all the limitations of claims 1-2 and 4.

Summary

23. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
February 19, 2008

/Jon M Lockard/
Examiner, Art Unit 1647